HUMAN HEALTH RISK ASSESSMENT FROM METHYMERCURY CONTAMINATED FISH

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DEQ is seeking information that will enable the agency to analyze the relationship between methylmercury contaminated fish and human ingestion by examining levels of risks to "vulnerable" (highly exposed or sensitive) human subpopulations due to fish ingestion and seafood related products. This information will be collected through use of a risk assessment model and would assist in performing an economic analysis of the "benefits" of requiring additional reductions of mercury emissions and the corresponding reduction of mercury contamination levels of fish and shellfish in Virginia waters.

Project Summary

Human exposure to methylmercury (MeHg) can result in adverse health effects on the cardiovascular, digestive, and nervous system. The primary source of chronic, low-dose exposure to methylmercury in the United States is through the consumption of contaminated fish (NRC 2000). This human health risk assessment is part of a larger study on utility attributable MeHg emissions in Virginia. While MeHg contamination can be found in both recreationally caught freshwater fish and commercially caught marine fish, it is not possible to estimate the VA utility attributable MeHg contamination in commercially caught fish species outside of Virginia.

This project will provide models of the risk of adverse health effects for the population (and sensitive sub-populations) of Virginia from the consumption of MeHg contaminated recreationally caught freshwater fish. Of the documented effects of methylmercury, some of the most severe are on the developing nervous system, therefore the known sensitive sub-populations include women of childbearing age, children, and high-end consumers of fish (EPA 2005).

Risk assessment models used by the U.S. Environmental Protection Agency in their analysis of the effectiveness of utility emission control (EPA 2005) and other states (Jakus et al. 2002) will be examined for relevance and applicability to Virginia. If possible, existing models will be modified to fit the data for Virginia. Good data exists for fish tissue concentrations (DEQ); however, some data collection is anticipated for assessing the consumption rates of fresh-water sport fish specific to Eastern Virginia. If necessary, intercept surveys will be performed to gather this data. Probabilistic risk assessment will be performed by running Monte-Carlo simulations and using Decisioneering Crystal Ball Risk Assessment software.

Background

Mercury (Hg) can be found in the environment in elemental, inorganic, and organic forms. Methylmercury (MeHg), one of the organic forms of mercury, is of concern because it bioaccumulates in the aquatic food chain and humans can be exposed to through the ingestion of contaminated fish (NRC 2000). While Hg comes from both natural and anthropogenic sources, the largest identified source of Hg emissions are coal fired power plants (EPA 1997a) Particles of inorganic Hg are emitted into the air can deposit onto the land or into waterbodies where microorganisms can convert the inorganic Hg into MeHg. The methylated form of mercury is easily absorbed by living organisms and biomagnifies up the food chain (ATSRD 1997).

MeHg is known to be highly toxic, as noted from the mercury poisonings in Minnamata, Japan and in Iraq. Health effects of these poisoning episodes included sensory and motor impairment in adults and mental retardation, cerebral palsy, deafness, blindness, and dysarthria in children

exposed in-utero (NRC 2000). In 1995, the EPA set the reference dose of 0.1 µg/kg-day based upon the poisoning episode in Iraq (from grain contaminated with a MeHg fungicide) (EPA 2005). However, since most of the U.S. population is more likely to be exposed to chronic-low dose MeHg exposure through the consumption of MeHg contaminated fish, the National Research Council was contracted to re-evaluate the RfD taking into consideration large epidemiological studies from the Seychelles, Faroe Islands, and New Zealand. The NRC recommended consideration of the 95% lower confidence limit for the benchmark doses for a number of neurological endpoints based upon the performance on neuropsychological tests. The end result of the NRC analysis was that the EPA kept the current RfD the same at 0.1 µg/kg-day (EPA 2005).

Task 1: Literature Review

The contractor shall conduct a literature review of existing studies in the areas of toxicology, environmental analysis of fish tissue and aquatic biota in relation to human health effects. Specifically, the contractor will do the following:

- *Evaluate studies from research institutes – United States Environmental Protection Agency's (EPA) Risk Assessment division, National Institute of Health (NIH), Health Effects Institute, Virginia Institute of Marine Science (VIMS) and peer reviewed journal publications - dealing with the effects of mercury and particulate pollutants on human health. The review shall include reviews of surrogate data-based analysis that have been performed, including the identification of risk assessment models that have utilized surrogate data.*
- *Conduct a review of the Virginia Department of Health (VDH) and EPA records of exposure to mercury and other public records to identify the "at-risk" subpopulations in the Commonwealth that face potential health risks from mercury.*
- *For the state of Virginia, gather fish mercury bioaccumulation data for species relevant to human consumption, consumption rates and patterns so as to generate their probabilistic distribution functions.*
- *Identify general health parameters that are used to understand human responses to varying levels of methylmercury intake as also specified in databases such as the EPA IRIS database (http://www.epa.gov/iris).*
- *Prepare a report summarizing the literature review that elaborates on existing research (and related assumptions) on dose-response relationships between fish tissue contamination of methylmercury and related effects to human health. The contractor shall provide a list of relevant websites, scientific journals, and studies reviewed in the report.*

A literature review will be conducted on literature relevant to the effects of methylmercury on human health; identifying the "at-risk" subpopulations in the Commonwealth that face potential health risks; mercury bioaccumulation data for fish species relevant to human consumption and their consumption rates and patterns; and similar methylmercury risk assessment studies. A preliminary literature review used in the preparation of this proposal is as follows.

References:

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(Task 1 continued)

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Seigneur C, Lohman K, Pai P, Heim K, Mitchell D, Levin L. 1999. Uncertainty analysis of regional mercury exposure. Water, Air, & Soil Pollution 112(1):151-162.

VDH (Virginia Department of Health) 2006. Frequently asked questions about mercury. Available: http://www.vdh.state.va.us/epi/publichealthtoxicology/Mercury.PDF [accessed 15 October 2006]

Task 2: Identify and test simulation model(s) that are applicable to Virginia

Based on the above literature and database reviews of current risk assessment studies, models and existing data on human consumption levels, rates and types of seafood consumed, the contractor shall identify appropriate simulation models that would fit the data available (input parameters) and if unavailable, develop a Virginia specific risk assessment model with surrogate data. A detailed cost breakdown of the various simulation models and other data procurement costs shall also be provided for DEQ's review and approval.

From the models examined (EPA 2005, Jones 2002), an acceptable approach to developing a test model would involve calculating the chronic daily intake (for an individual at a specified consumption level and a specified fish tissue MeHg concentration level), and dividing the chronic daily intake by the RfD for a specified health endpoint to get a hazard quotient, where a value of greater than one represents incremental exposure greater than the RfD. (According to EPA (2005), in the model they developed "a value of 1 represents an absolute exposure greater than the RfD when background exposures are considered.")

A basic description of the EPA model is:

$$\frac{(\text{consumption rate} * \text{fish tissue MeHg concntrn} * \text{correction factor for cooking})/\text{body weight}}{\text{RfD}}$$

Another model which may be applicable to Virginia is the "Maryland Model" used to estimate the benefits and costs of fish consumption advisories for mercury (Jakus et al. 2002). In this model, in addition to comparing the estimated chronic daily intake to the EPA's RfD, the investigators converted the daily dietary MeHg intake (calculated from consumption rate and contamination levels) into blood level concentrations of MeHg and hair concentrations of MeHg. With the estimated blood and hair concentrations, it was possible to compare these estimates to bench mark doses (BMDs) of various health effect endpoints noted in the epidemiological literature on this topic (adult paresthesia, performance on several childhood neuropsychological tests, MeHg related acute myocardial infarction, all-cause mortality, and average change in systolic and diastolic blood pressure in children 7 years of age) and estimate the change in these endpoints and the health benefits from a reduction in the consumption rate. Because Jakus et al. (2002) had specific data on the recreational striped bass fishery they were able to estimate the number of people who were exceeding the MD fish consumption advisories and the number of people exceeding the EPA's RfD.

All of the above mentioned models will be examined to see if they are appropriate to the data available. Most likely, elements of the above model will be incorporated into Virginia specific risk assessment model.

The limitations of using point estimates in risk assessment models have been noted in several publications (Lipfert et al. 1994, Hammonds et al. 1994). In addition, Bayesian probability analysis has been noted to enhance belief in risk assessments (Newman and Evans 2002). For the risk assessment model we will use Monte Carlo simulations using the probability distributions and 95% confidence intervals of the following input parameters (assumptions):

(Task 2 continued)

- **Fish tissue MeHg concentrations**. For this analysis we will use existing fish tissue data from the DEQ to estimate the probability distribution of contamination in fish of concern:
    - largemouth bass, redear sunfish, bowfin, chain pickerel, white catfish, blue catfish, bluegill sunfish, yellow bullhead catfish, carp, longnose gar (VA DEQ 2006 and VDH 2006).

- **Human consumption rates of freshwater fish**. Virginia specific, watershed specific, and species specific freshwater fish consumption data is scarce. One possible source of consumption rate estimates comes from a 2001 study on the James River in which 143 personal interviews of recreational anglers were conducted (Jones 2002). Using this data it would be possible to estimate the distribution of species consumed, amount consumed, and frequency consumed in the tidal freshwater James River; however, it most likely would be necessary to conduct additional surveys in another affected watershed to test if the existing James River consumption figures are valid estimates for all freshwater anglers in Virginia's coastal plain. If the results of the 2001 James River Survey are determined to be significantly different than a trial survey from an additional watershed (e.g. Piankatank or Blackwater Rivers), additional surveys could be conducted in one or more of the remaining affected watersheds. Based upon the parameters of the 2001 tidal freshwater James River study (number of survey sites=7, time at each site= approximately 2 hrs, sites sampled per day= 3 or 4, and number of days sampling = 18 days), it is estimated that surveys from other watersheds can be procured for **$5000**. Models will include overall consumption estimates for Virginia freshwater fish consumers and consumption estimates for the sensitive subgroups (women of childbearing age, children, high-end fish consumers.)

- **Population size of Virginia freshwater anglers**. By using existing information from VA DGIF (freshwater fishing license data) and VA DCR (Virginia Outdoors Survey) to estimate the number of recreational freshwater anglers in the affected areas (e.g. from the Virginia Outdoors report – 19.9% of Virginian's reported participating in freshwater fishing, and 80.2% of their freshwater fishing took place in VA)

The Monte Carlo Simulations and risk assessment model will be done with Decisioneering Crystal Ball Risk Analysis software and ModelAssist Advanced for Crystal Ball - total software price **$560.** Crystal Ball Risk Analysis is the probabilistic modeling software that was used in the human health risk assessment associated with the consumption of PCB-contaminated fish from the tidal freshwater James River, Virginia (Jones 2002). Crystal Ball works with data in MS Excel spreadsheets and expands the analysis capability beyond the traditional point estimates, range estimates, and "what-if" scenarios, by helping to define the uncertain variables. From a given range of values and probability distribution, Crystal Ball will run thousands of simulations to determine the probability that a certain forecast value will fall within a specified range. The advantage to this type of risk analysis is that the probability of a particular outcome is calculated in addition to point and range estimates. (Decisioneering 2006).

Task 3: Provide a prototype model applicable to representative region of Virginia

Based on the literature review, the contractor shall initially develop a prototype model with baseline year conditions and submit the prototype to DEQ for review of the implicit assumptions and parameter values. Upon approval of the baseline model settings, the contractor shall provide simulated estimates of the health risk associated with fish consumption to "at-risk" Virginia subpopulations, taking into account the Department of Health's fish advisory standards. Furthermore, the model should identify the probabilities at which the "at-risk" groups of the population are at risk given: Low, Medium and High levels of methylmercury intake. In the absence of sufficient data, development of a representative model that fits a certain local region within Virginia would be acceptable. The contractor shall also explore other avenues or models to develop best-guess estimates to make projections on the range of methylmercury intake (based on emission and deposition information), in the event that adequate fish tissue data is missing. The model should be validated through an evaluation of computed risk estimates and submitted to DEQ for review. DEQ may include a group of experts from the areas of fish tissue analysis, toxicology and human health to review the validity of the model.

The prototype model developed will be submitted for approval to DEQ with the baseline year conditions/ assumptions for the current fish tissue MeHg concentrations (from VA DEQ 2006). Using inputs from concurrent research involving Hg emissions/ deposition/ fish tissue uptake, it will be possible to input projected fish tissue MeHg concentrations into the model to forecast the hazard quotient for an individual consumer of freshwater fish at a range of consumption levels, including the Virginia Department of Health's fish consumption advisories level, and to estimate the health risks for the sensitive subpopulations (women of childbearing age, high-end fish consumers).

The model provided will be applicable to affected regions in Virginia: Blackwater River (Southampton and Isle of Wight Counties), Dragon Run Swamp/Piankatank River, Great Dismal Swamp Canal and Lake Drummond, Mattaponi River and its tributary Herring Creek, Pamunkey River, Chickahominy Lake and four small lakes. Mercury contamination in other regions in the state is due to industrial accidents. The eastern rivers have common hydrographic characteristics making them susceptible to methyl mercury contamination.

(Currently The Food and Drug Administration has set an action level of 1 part of methylmercury in a million parts (ppm) of seafood. The Virginia Department of Health guideline for issuing a fish consumption advisory for mercury is 0.5 ppm.) (VDH 2006)

Task 4: Report of risk assessment analysis and potential impact to human health

Using an appropriately working and validated risk assessment model, DEQ shall be given an analysis of the range of intakes of methylmercury by "at-risk" sub-groups of Virginian population and associated probabilities of being at risk to exposure and severe human health effects. Specifically, the DEQ expects that the contractor shall use the risk assessment model to generate estimates of risks to the sensitive sub-groups of Virginia's population due to exposure to different levels of methylmercury in fish tissue in response to baseline, Phase 1 (2010) and Phase 2 (2015 and 2018) level of emissions (and consequent levels of deposition). A preliminary report shall be submitted to DEQ that consists of: risk assessment model, input and raw data files, specification of related assumptions and final results. Within four weeks of receiving comments from DEQ, the contractor will make necessary changes and/or modify and submit a final report to the Contract Administrator that comprises of the literature review, simulation model and assumptions, copy of the data used and final results.

The Final Report will describe the method used to determine risk: a dose-response assessment of various health effect endpoints from the literature review, an exposure assessment based upon Virginia specific fish tissue MeHg concentrations and Virginia specific consumption data (if sufficient data exists – if not, and consumption data is not procured, we will use the EPA recommended fisher consumption rates of 8g/day (mean) and 25g/day (95^{th} percentile) (EPA 2005), and finally a risk characterization.

This risk characterization will be based upon the probability distributions generated for consumption rates and population estimates. These exposure probabilities will be compared with the RfD for human health effect endpoints (use the EPA's RfD of 0.1 μg/kd-day) to estimate the numbers of Virginians exceeding the RfD under baseline conditions and under future conditions in which utility emissions of mercury are capped/ reduced.

Task 5 – Data Archival and Transfer of Modeling Files

All relevant information required to corroborate the study findings will be provided in an electronic format approved by DEQ. Transfer of data may be facilitated through the combination of a project website and the transfer of large databases via overnight mail. Database transfers will be accomplished using an ftp protocol for smaller datasets, and the use of IDE and Firewire disk drives for larger data sets.

All data and models will be provided to DEQ in digital format.

Task 6 – Quality Assurance Plan

The contractor shall develop a Quality Assurance Project Plan (QAPP) to ensure that the modeling study is scientifically sound, robust, and defensible (i.e., the QAPP should specify the requirements needed to ensure the quality of the results produced by the models).

All data collected and entered into spreadsheets will be checked for accuracy. The statistical analysis and models used will be validated by a staff member from the Department of Statistical Science and Operations Research at Virginia Commonwealth University.

Task 7 - Project Management

Effective communications and free flow of information between DEQ and the contractor is essential to accomplish the modeling necessary for this project. The objectives of this task are to manage project activities, participate in conference calls, manage the contract and provide general oversight and overall quality assurance. The contractor shall submit a general project report plan during the first month of the contract. The contractor will review progress against this work plan monthly during the project and will revise the work plan as needed. The following management activities, at a minimum, shall be performed as part of this task:

Prompt response to questions raised by DEQ.

- *Timely submittal of all deliverables.*
- *Participation in scheduled conference calls to be held approximately biweekly as well as expected ad hoc conference calls to be held as needed.*
- *Participation in up to 4 meetings (1 day per meeting) per year for purposes of project planning and review of project progress.*
- *Development and refinement of the project Scope of Work in cooperation with the DEQ modeling team and other project representatives.*
- *Preparation of monthly progress reports.*
- *Development and implementation of the modeling analysis in accordance with the modeling protocol and Quality Assurance Project Plan (QAPP).*

Timeline:

1. **Summary of Literature Review** – A summary of the literature review and final report to detail, document and summarize the results of the literature review and summary of existing risk assessment studies and related simulation models on or around **March 15th, 2007.**

2. **Draft Report of risk assessment model and results –** A preliminary report will be submitted to DEQ that consists of the risk assessment model and related assumptions, data used and the results by **June 15th 2007.**

3. **Final Report** – Formal presentation of final report that includes identification of the research problem, literature review, risk assessment model and results along with appropriate electronic files, data used and the model on or around **September 30th 2008 and incorporate minor revisions or changes by October 15th 2007**.

Qualifications of staff assigned to this task:

The work on this project will be carried out by a team of three faculty and a graduate student in the Center for Environmental Studies. Dr. Peter deFur will be the Principal Investigator, and the primary researcher will be Rachel Bullene, a graduate student in the Center. Two CES faculty members, Drs. Greg Garman and Cliff Fox will be advisors on this work. The three faculty members have extensive experience with all aspects of this project, including fisheries biology, toxicology, risk assessment, public surveys, as well as the ecosystems of tidal tributaries of Eastern Virginia.

Faculty from the Department of Statistical Sciences and Operations Research and the School of Medicine (Department of Epidemiology and Community Health) will be available for consultation and advice on the risk assessment and analysis of data.

The Principal Investigator, Dr. Peter L. deFur is an affiliate Associate Professor in the Center for Environmental Studies at VCU. Dr. deFur also provides consulting services to government agencies and community groups around the country, principally on contaminated sites. A full CV is attached. Most of the contaminated sites include riverine systems contaminated with mercury, PCB's, dioxins, etc. Dr. deFur has extensive experience with risk assessment, both human health and ecological, and has extended his work to cumulative risk assessment. He has been involved with human health risk assessments regarding the consumption of contaminated fish on river systems throughout the country. Dr. deFur's experience with health risk assessment from contaminated fish includes the following:

- dioxin contaminated fish in Virginia
- PCB contaminated fish on the Hudson River, NY
- PCB contaminated fish on the Housatonic River, MA
- PCB and metal contaminated fish from the Duwamish River, WA
- PCB contaminated fish in the Spokane River, WA
- PCB contaminated fish in the Delaware River, DE
- Dioxin and metal contaminated fish from Bay St. Louis, MS

Dr. deFur has also participated in numerous related activities regarding the problem of methyl mercury contaminated fish. He was a member of the National Research Council Board on Environmental Studies and Toxicology and served as liaison to the NAS committee on methylmercury. He has been an official peer reviewer for EPA's health standard on PCB's, and EPA's assessment of the health risks for dioxin; both compounds are fish tissue contaminants throughout the country.

At VCU, Dr. deFur teaches a graduate level course in Ecological Risk Assessment that includes basic quantitative risk assessment and probabilistic (i.e. Monte Carlo) approaches. He has also served on numerous professional working groups through the Society for Environmental Toxicology and Chemistry (SETAC) that addressed the use of probabilistic risk assessment. These are listed in deFur's CV. Over his career, Dr. deFur has also conducted lab and field research on the rivers that are of interest in this project (James, Mattaponi, Pamunkey, etc.).

Dr. Greg Garman is the Director of the VCU Center for Environmental Studies and conducts research on fish populations in Virginia, with a special emphasis on the fish of the James River. Dr. Garman was lead investigator on an EPA grant to investigate contaminants in catfish from the James River. He was also on the thesis committee of a previous VCU student (Jennifer Jones) who investigated fish consumption on the James River. He has extensive experience with fisheries of the James River, and has conducted surveys of catfish populations and condition for many years. Dr. Garman has many years of experience conducted ecological investigations and fish population surveys on the tidal estuaries of Eastern Virginia that are the Dr. Garman's biographical sketch is attached.

Dr. Cliff Fox is the Assistant Director of the Center for Environmental Studies and investigates environmental policy. He has extensive experience in environmental surveys and helped design several surveys assessing fish consumption. He worked on the design and implementation of the fish consumption survey for CES graduate student Jennifer Jones who completed her thesis research on consumption of mercury contaminated fish from the James River. His biographical sketch is attached.

Task 8: Other Tasks as Assigned

There is the possibility that during the course of the project additional tasks not originally RFP #07-03-JW 17 identified will need to be completed. The costs associated with any additional tasks will be negotiated between the Contract Administrator and the contractor as the tasks are defined.

The project team will be available for additional work as requested pending negation with DEQ staff.

BUDGET

	Budget Amount	**Budget Narrative**
Personnel	2,625	10% of advisory faculty time
Fringe	207	Fringe rate is 7.9%
Supplies	560	Crystal Ball software and Model Assist software (2 year license)
Travel	882	3 trips to Washington D.C. for meetings, one trip to Raleigh, NC for a meeting, and travel expenses for 2 people to attend a conference in Blacksburg, VA.
Training	1,306	Tuition and fees for "Ecological Risk Assessment Class," 3 credit graduate level course at VCU
Data Collection	5,000	Fish consumption data acquisition - reimbursement for graduate students to do intercept surveys at 6 locations in Eastern Virginia
Total Direct	10,580	
Indirect	0	
TOTAL	10,580	